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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,778	04/20/2001	James N. Herron	3278.1US	3373

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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/839,778	HERRON ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on September 27, 2006 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 8-9, 13-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackowski, 5,747,274. Jackowski discloses a method of concurrently evaluating the

presence of a plurality of analytes (col. 29, line 35-38, disclosing detecting presence and amount of markers, and simultaneous detection and measurement); in a single sample (col. 22, lines 14) applied to a single assay device (col. 8, lines 59-65), at least one analyte having known parameters indicative of an acute metabolic or disease state, (see column 4, lines 32 - column 8, line 31, and column 19, lines 8-14); substantially determining concentrations of each of the analytes (col. 29, lines 38-39); continuing the determination until the analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state, (see column 29, lines 51-63); and reporting said determination in an amount indicative of the metabolic or disease state, (see column 29, lines 51-63).

As to claim 2, evaluating the presence of at least one other analyte continues after the report in order to accurately determine the presence or concentration of the analyte, (see column 22, lines 1-12).

As to claim 3, the method further comprises evaluating binding of the analytes to corresponding reactive elements over a plurality of time points, see column 22, lines 6-12.

As to claim 4, the determination is effected by reacting at least one analyte with a corresponding reactive element, see column 19 lines 15-22.

As to claim 5, the determination includes exposing the sample to the reactive elements, see column 11, lines 1-12.

As to claim 6, each reactive element is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 8, the reactive elements are arranged in a pattern on the waveguide surface, (col. 30, line 67, col. 31, lines 8-9, and lines 15-16, see figure 10, disclosing the arrange of the antibodies, i.e., reactive elements.) It is noted that the antibodies (24, 28, 32) are disclosed in a pattern in figure 10, and the support is considered to be a waveguide surface. It is noted that Applicants do not recite any structural elements to the waveguide surface such that it would distinguish from the Jackowski disclosure. Moreover, it is noted that use of capillary action for flow of serum or plasma as disclosed by Jackowski (col. 30, line 65) does not prevent the three different antibodies from being detected concurrently. That is, the flow of a sample and the detection step are two distinct steps.

As to claim 9, the determination includes introducing a light beam including at least one wavelength for stimulating a light signal from the reactive element when the reactive element has coupled with the analyte, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 13, the analyte is a marker released from cardiac tissue only after a myocardial infarction, see column 1, lines 63-67.

As to claim 14, the marker comprises myoglobin, see column 4, line 36-5.

As to claim 15, the analyte is a cardiac specific marker, see column 1, lines 63-67.

As to claims16-19, the analyte comprises troponin as claimed, see column 7, lines 34-37.

As to claim 20, the analyte comprises creatine kinase, see column 5, lines 29-31.

As to claim 21, the creatine kinase comprises CK-MB, see column 5, lines 29-31.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackowski, 5,747,274, in view of Sawai et al., 4,224,304.

Jackowski discloses the invention substantially as claimed (see above.) Jackowski provides several examples of methods to determine the extent or amount of binding between the antibodies and markers (see for example, col. 28, lines 8-38.) Jackowski teaches various means of detection techniques, including measuring light signals (col. 28, lines 1-11). Jackowski teaches that various different detection and measurement technologies for determining the presence and amount of a marker or analyte may be used in the invention (col. 29, lines 31-36.)

However, Jackowski does not disclose that the continuation step includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte (claims 7 and 12); nor that the light signal is indicative of a rate of reaction between the analyte of interest and the reactive element (claims 10 and thus its dependent claim 11.)

Sawai et al., 4,224,304, discloses a method for quantitative determination of antigens in a sample by evaluating the rate of increase in absorbance or percent absorption per unit time (col. 11, lines 36-44.) Thus, Sawai et al. teach method of measuring light signal generated from the reaction of an analyte with a reactive element, correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte, wherein the light signal is indicative of a rate of reaction between the analyte and the reactive element as claimed by Applicant.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the method taught by Sawai to determine the amount of analyte binding in the Jackowski method as a known alternative method for determining the extent or amount of binding between an antibody and an analyte. In view of the teachings of Jackowski and Sawai one of ordinary skill in the art would have a reasonable expectation of success.

Response to Arguments

Applicants' arguments filed September 27, 2006 have been considered but are not persuasive.

Applicants argue that the Board of Patent Appeals and Interferences read Jackowski as disclosing a method that includes the "substantially simultaneous" evaluation of a plurality of analytes, pointing to the Board's decision on pages 6-7. Applicants also state that the Board also noted that "concurrent" evaluation is different

from "substantially simultaneous" evaluation, pointing to page 6 of the Board's decision on page 6.

Applicants' arguments however are not persuasive. Page 6 of the Board's decision (first full paragraph) only states that Applicant's term "substantially simultaneously" reads on Jackowski's definition of simultaneous, i.e., a shortened period of time. It does not appear that the Board interpreted Jackowski to be a method of "substantially simultaneous" (that is, to the exclusion of concurrent) as asserted by Applicants, but rather that Jackowski *encompasses* substantially simultaneously, such that Applicant's use of the term "substantially simultaneously" reads on Jackowski's definition of simultaneous.

Moreover, page 6, third full paragraph to page 7, first line, of the Board's decision states:

> 'The examiner finds, however, that "the term 'simultaneous' as used by Jackowski encompasses a concurrent evaluation of the sample, because Jackowski indicates that the term 'simultaneous' includes an evaluation within a given period of time (col. 22, lines 8-9), and a concurrent evaluation is within a given period of time" and does not exclude concurrent analysis. Answer, page 7. In agreement with the Examiner, we note that the claims before us

do not require concurrent evaluation, they require "substantially simultaneous" evaluation'.

Thus, it appears from this statement that the Board had agreed with Examiner on the point that the term 'simultaneous' as used by Jackowski encompasses a concurrent evaluation of a sample because Jackowski indicates that the term 'simultaneous' includes an evaluation within a given period of time, and a concurrent evaluation is within a given period of time and simultaneous does not exclude concurrent analysis.

With respect to Applicants' statement that the Board also noted that "concurrent" evaluation is different from "substantially simultaneous" evaluation, pointing to page 6 of the Board's decision on page 6, Examiner notes that the Board is pointing out that *Applicants'* claims (as presented to the Board) did not require concurrent evaluation (because they recited "substantially simultaneously", rather than simultaneously, or concurrently). It does not appear however that the Board was interpreting *Jackowski* to be a method of "substantially simultaneous" but excluding simultaneous or concurrent. (See the Board's decision on page 6, last two lines to page 7, first line, stating "In agreement with the Examiner, we note that the claims before us do not require concurrent evaluation, they require "substantially simultaneous" evaluation.) In other words, the Board was distinguishing between the term concurrent and Applicants' claims reciting "substantially simultaneously", as opposed to distinguishing between the term concurrent and the term simultaneous as used by Jackowski. It is also noted that Examiner had also stated this point in the Examiner's answer.

Applicants also argue that claim 8 is also allowable because Jackowski does not describe the capture molecules to be in a pattern on the surface of a waveguide. Applicants state that the citations given by Examiner in the rejection only state the possible use of a variety of optoelectronic detection systems (col. 27, lines 49-49), that a ligand and its receptor may be covalently immobilized on the optical surface of a planar, fused-quartz waveguide" (col. 28, lines 1-11), and splitting excitation light into two channels (col. 29, lines 1-29). Applicants' argument are not persuasive because, as noted above in the rejection, the antibodies (24, 28, 32) are disclosed in a pattern in figure 10, and the support is considered to be a waveguide surface. Applicants do not recite any structural elements to the waveguide surface such that it would distinguish from the Jackowski disclosure. Moreover, it is noted that use of capillary action for flow of serum or plasma as disclosed by Jackowski (col. 30, line 65) does not prevent the three different antibodies from being detected concurrently. That is, the flow of a sample and the detection step are two distinct steps.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A.L.

ANN YEN LAM
PATENT EXAMINER